

Cleaning Product Ingredient Safety Initiative: Exposure **Assessment for Ingredients**

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Goal: Screening level risk assessment for every identified ingredient in consumer cleaning products for member companies

- Task 1: Compilation of member product ingredients
- **Task 2:** Hazard datasets for ingredients
- Task 3: Exposure assessments based on product use
- Task 4: Screening-level risk assessment for each cleaning product ingredient
- **Task 5:** Electronic clearinghouse for presentation of findings and supporting data
- Task 6: Public communications program

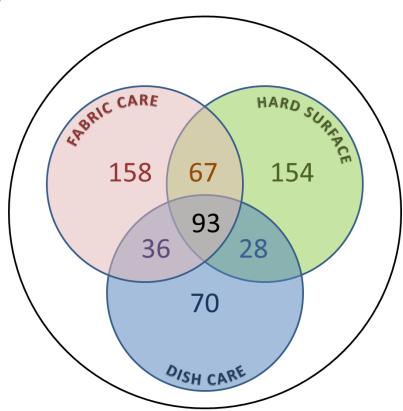


- Task 1: Ingredient Inventory
 - 900 products from 12 companies
 - 13,000 listed ingredients; ~1,000 unique ingredients
 - Naming consolidation and consistency
 - The inventory is available online: http://www.cleaninginstitute.org/science/ingredient_inventory.aspx

Ingredient Inventory			
Ingredient Name	CAS Registry Number(s)		
Abies Alba Leaf Oil	8021-27-0 8021-28-1		
Abies Balsamea(Balsam Canada) Extract, Abies Balsamea(Balsam Canada) Needle Oil, Abies Balsamea (Balsam Canada) Resin	8007-47-4 85085-34-3		
Acetic Acid	64-19-7		
Acetic acid, ammonium salt	631-61-8		
Acetic acid, calcium salt	62-54-4		
Acetic acid ethenyl ester, polymer with oxirane	25820-49-9		
Acetic acid, magnesium salt	142-72-3		



- Task 1: Ingredient Inventory
 - 900 products from 12 companies
 - 13,000 listed ingredients; ~1,000 unique ingredients





- Task 2: Assembly of Hazard Data
 - Goal: Gathering of complete SIDS dossier for all identified ingredients from publicly-available sources; focus on endpoints critical for risk assessment (chronic, reproductive/ developmental)
 - Primary data sources were ECHA CHEM, HPVIS, OECD HPV
 - Read-across was critical
 - Sufficient data for risk assessment: 61%
 - Identified as low hazard substances: 20%
 - Further investigation required: 16%



- Task 2: Assembly of Hazard Data
 - Currently available data can be accessed through the Web Portal

http://www.cleaninginstitute.org/science/compilation_of_hazard_datasets.aspx

Available Hazard Data /Hazard Data Available for Chemical Similar to

Alcohol

In some instances during the hazard data collection process, searching chemical hazard data sources1 for an ingredient resulted in both primary hazard data (i.e., data developed specifically for the ingredient under study) and hazard data from a similar chemical substance (i.e., read-across hazard studies) being identified. Read-across is a process by which one or more properties of a given chemical are inferred by comparison of that chemical with a chemical(s) of similar molecular structure(s) and physicochemical properties, for which the properties of interest are known. For example, if chemical A (the target chemical) has no available hazard data for acute oral toxicity, chemical B (the source chemical) can be used to predict the same endpoint based on its similar structure, physicochemical properties, or mode or mechanisms of action. Read-across approaches are often integrated into publicly available hazard data sources such as REACH dossiers and the HPVIS database. Read-across data sources were recorded when searching for hazard data for specific ingredients, and provide a valuable and technically defensible source of data.

Both primary hazard data and read-across hazard data for Alcohol was acquired from the following sources:

ECHA CHEM hazard data and read-across dara for Alcohol (64-17-5) HPVIS hazard data for Alcohol (64-17-5) OECD HPV hazard data for Alcohol (64-17-5)

Recurrent database updates planned

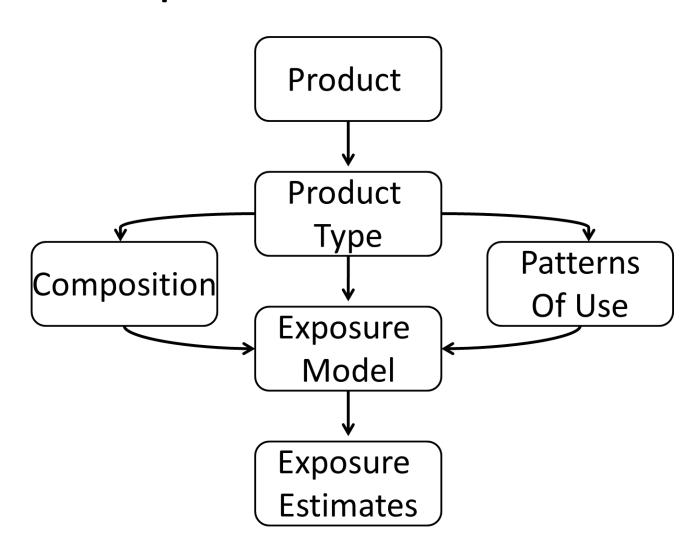
¹To learn about the primary and secondary chemical hazard databases that were utilized, please see the ACI Compilation of Hazard Datasets Methodology Document.



- Task 3: Exposure Assessment
 - Tier 1 screening level
 - Connect product usages to ingredients to exposure scenarios, yielding exposure estimates
 - Typical product formulation
 - Habits and practices
 - Intended uses
 - Aggregate exposures: multiple product usages

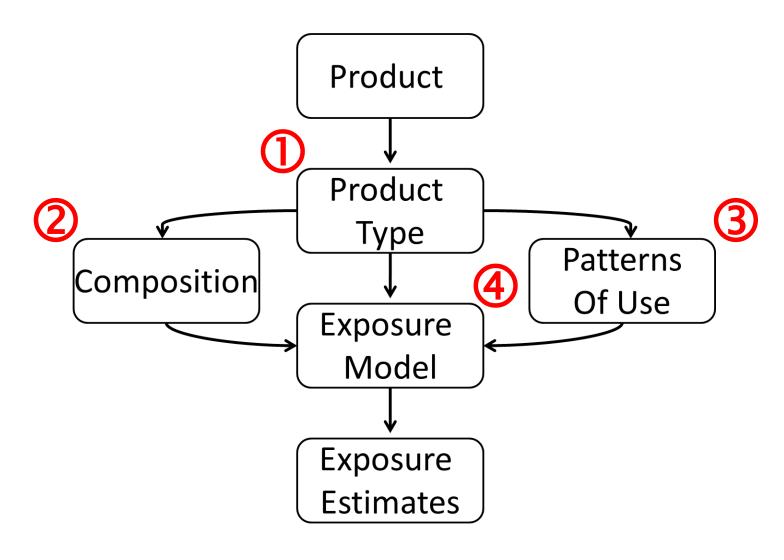


Task 3: Exposure Assessment





Task 3: Exposure Assessment



① Product Types

- Scope of CPISI: Dish care, laundry care, hard surface cleaners
 - Dish care (6): hand/machine -- liquid/powder/ tablet
 - Laundry care (22): softeners, detergents,, pretreatments, fresheners -- liquid/powder/ tablet/gel
 - Hard surface (8): all-purpose, dilutable/ concentrated -- sprays/gels, liquids/powders
- Each product type dictates:
 - Formulation
 - Usage → exposure pathways/models



© Composition: Product Formulations



Ingredient	Use Class	Example	Concentration
LAS	Surfactant	25155-30-0	1-5%
Nonionics	Surfactant	3055-99-0	0.1-0.5%
Polymer	Polymer	25035-69-2	3.5-5%
Fragrance	Fragrance	8022-96-6	<1%
Water			To 100%

- Product formulation data is gathered and coalesced around product types
 - Sources: product info sheets, trade literature, company surveys, etc.

© Composition: Product Formulations

- Concentration ranges are gathered for specific ingredients and/or functional use classes
 - EPA's Design for Environment: surfactants, solvents, chelators, enzymes, polymers (13)
 - New functional use classes beyond DfE added as necessary (762 ingredient-FC associations)
 - Use of chemical category information generated in Tasks 1 and 2 to provide for read-across based gap-filling on concentration data



③ Exposure: Habits and Practices

- How are these products used in real-world scenarios?
 - Habits and practices data compiled by American Cleaning Institute (formerly the SDA)
 - Frequency of use (uses/day)
 - Laundry detergents: 1/day
 - Liquid dish detergent: 1-3/day
 - Amount used (g/use)
 - Liquid APC: 41-76 g/use
 - Time used

4 Exposure Models

 Intake calculations: the intersection of product types, product usage, and product formulation

- Dermal
 - Direct: Contact with soaps while washing dishes
 - Indirect: Laundry product residue in clothing
- Oral (indirect only)
 - Contact with residue on washed dishes
 - No direct (intended uses)
- Inhalation
 - Powders, sprays

4 Exposure Models

Intake calculations: Examples

 $A \times PR \times PT \times CF \times DA$

BW

Dermal: indirect

Laundry care: wearing clothes

 $FQ \times CA \times PC \times FT \times CF \times TF \times DA$

BW

Dermal: direct

Laundry care: hand-washing clothes

 $C' \times Ta' \times Sa \times CF$

BW

Oral: indirect

Dish care: residue after washing

A: amount used

PR: percent retained on clothing

PT: percent transferred

CF: conversion factor

DA: dermal absorption

FQ: frequency of use

CA: dermal contact surface area

PC: product concentration

FT: film thickness on skin

TF: Time factor

C': product concentration

Ta': water on dish after rinse

Sa: area of dish contacting food

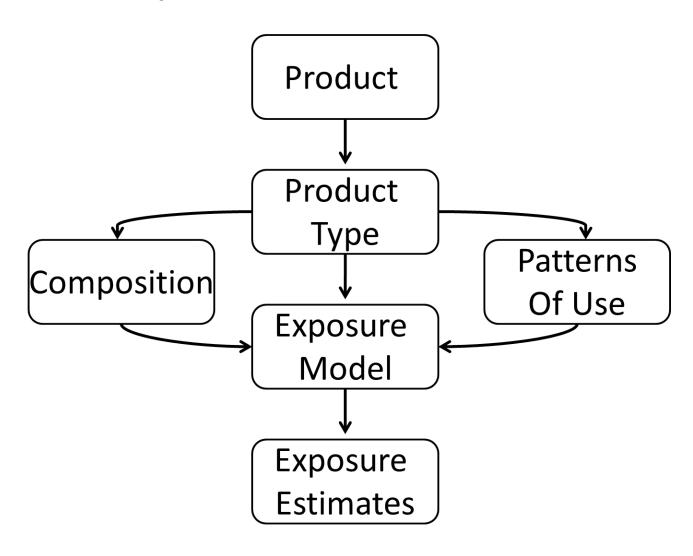


4 Exposure Scenarios

- Consistent with previous assessments, exposure scenarios will focus on women and children
 - Conservatism in screening level estimates
 - Occupational: different formulations, different exposure patterns
 - Potential future effort



Task 3: Exposure Assessment





Exposure: Opportunities for Refinement

- Formulations: concentration at point of exposure
 - Use market penetration data in combination with ranges or specific data to generate distributions for point-of-exposure concentration
- Habits and Practices
 - Frequencies of use, amount used, dermal contact areas
 - Dermal absorption
- Body weights
- Additional exposure scenarios and products



CPISI: Conclusions and Future Efforts

- Ingredient inventory and sources for hazard data available online through CPISI Web Portal
- Exposure assessments ongoing: tiered approaches deployed as necessary following risk characterization (CPISI Task 4)
 - Refinements: Probabilistic approach to formulations, product usage data (habits and practices), body weights, etc.
- Further deployment of computerized exposure models (ECETOC TRA, EUSES, CONSEXPO)
 - NA vs. EU exposure parameters and formulations